

What is claimed is:

1. A medical introducer device comprising:
  - (a) a single-layer, peelable PTFE sheath having a bore extending therethrough and that does not include mechanically produced skiving for longitudinal splitting of the sheath, the sheath thermally cured to provide a peel strength of at least about 0.5 lbs with a standard deviation of no greater than about 0.40; and
  - (b) a hub unit attached at a proximal end of the peelable sheath which facilitates splitting of the peelable sheath upon application of an effective shearing force thereon.
2. The device of claim 1 wherein the sheath has a peel strength of at least about 0.70.
3. The device of claim 1 wherein the sheath has a peel strength of at least about 1.0.
4. The device of claim 1 wherein the sheath has a peel strength standard deviation of no more than about 0.30.
5. The device of claim 1 wherein the sheath has a peel strength standard deviation of no more than about 0.20.
6. The device of claim 1 further comprising a plurality of wing portions attached to the hub unit on opposing sides for grasping the hub unit.
7. The device of claim 1 wherein the peelable sheath comprises a detectable material capable of external visualization.

8. The device of claim 1 further comprising a needle or dilator assembly extending longitudinally within the bore of the peelable sheath

9. A medical introducer device comprising:

(a) a multi-layer, peelable PTFE sheath having a bore extending therethrough, and that does not include mechanically produced skiving for longitudinal splitting of the sheath, the sheath thermally cured to provide a peel strength of at least about 0.5 lbs with a standard deviation of no greater than about 0.40; and

(b) a hub unit attached at a proximal end of the peelable sheath which facilitates splitting of the peelable sheath upon application of an effective shearing force thereon.

10. The device of claim 9 wherein the sheath has a peel strength of at least about 0.70.

11. The device of claim 9 wherein the sheath has a peel strength of at least about 1.0.

12. The device of claim 9 wherein the sheath has a peel strength standard deviation of no more than about 0.30.

13. The device of claim 9 wherein the sheath has a peel strength standard deviation of no more than about 0.20.

14. The device of claim 9 further comprising a plurality of wing portions attached to the hub unit on opposing sides for grasping the hub unit.

15. The device of claim 9 further comprising a needle or dilator assembly extending longitudinally within the bore of the peelable sheath

16. The device of claim 9 wherein the multi-layer, peelable sheath comprises a thermally stable outer layer and at least one inner layer.

17. The device of claim 16 wherein the inner layer comprises a detectable material capable of external visualization.

18. The device of claim 16 wherein the thermally stable outer layer of the peelable sheath comprises a pigment.

19. The device of claim 18 wherein the outer layer and inner layer of the peelable sheath each comprise visibly distinct pigments.

20. A method of manufacturing a single-layer, peelable PTFE sheath that does not include mechanically produced skiving for longitudinal splitting of the sheath, the method comprising:

- (a) providing a PTFE preform material;
- (b) extruding the preform material into tubing;
- (c) drying the tubing; and
- (d) curing the tubing to provide a peel strength of at least about 0.5 lbs with a standard deviation of no greater than about 0.40.

21. The method of claim 20 further comprising adding a detectable material to the preform blend in an amount sufficient to facilitate external visualization by X-ray or fluoroscopic procedures.

22. The method of claim 20 further comprising:
- (a) affixing a hub unit onto a proximal end of the peelable sheath;
  - (b) attaching a plurality of wing portions to opposing sides of the hub unit;
- and
- (c) tipping the peelable sheath at a distal end thereof.
23. The method of claim 22 wherein the tipping comprises thermally treating the sheath.
24. A method of manufacturing a multi-layer, PTFE peelable sheath that does not include mechanically produced skiving for longitudinal splitting of the sheath, comprising:
- (a) preparing a first preform PTFE material for forming the inner layer of the peelable sheath;
  - (b) preparing a second preform PTFE material for forming the outer layer of the peelable sheath;
  - (c) combining the first preform material and second preform material blend into a two layer preform;
  - (d) extruding the two layer preform into tubing;
  - (e) drying the tubing; and
  - (f) curing the tubing using a precision sintering process.
25. The method of claim 24 further comprising equilibrating the first preform material and second preform material prior to their combination.
26. The method of claim 24 further comprising adding a detectable material to the first preform blend in an amount sufficient to facilitate external visualization..

27. The method of claim 24 further comprising adding a colored pigment to at least one of the first preform material and the second preform material.

28. The method of claim 24 further comprising:

(a) affixing a hub unit onto a proximal end of the peelable sheath;

(b) attaching a plurality of wing portions to opposing sides of the hub unit;

and

(c) tipping the peelable sheath at a distal end thereof.

29. The method of claim 28 wherein tipping the peelable sheath comprises using a thermal process.

30. A method of introducing a catheter or guide wire into a patient comprising:

(a) providing a medical introducer device of claim 1;

(b) piercing and dilating the vasculature of the patient using the needle or dilator assembly;

(c) inserting the catheter or guidewire through the bore of the peelable sheath into vasculature of the patient;

(d) applying cooperating forces to the wing portions of the hub unit to axially shear the peelable sheath; and

(e) removing the peelable sheath from the vasculature of the patient.

31. A method of introducing a catheter or guide wire into a patient comprising:

(a) providing a medical introducer device of claim 9;

(b) piercing and dilating the vasculature of the patient using the needle or dilator assembly;

(c) inserting the catheter or guidewire through the bore of the peelable sheath into vasculature of the patient;

(d) applying cooperating forces to the wing portions of the hub unit to axially shear the peelable sheath; and

(e) removing the peelable sheath from the vasculature of the patient.